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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,737	07/31/2003	Marvin S. Antelman	10514-024-999	6939

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,737	ANTELMAN, MARVIN S.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/31/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/1/2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the tetrasilver tetroxide, does not reasonably provide enablement for treatment, prevention or management of all dermatological skin conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to preventing, treating or managing one or more dermatological skin diseases in a patient's skin with tetrasilver tetroxide, which is substantially free of added persulfate.

The state of the prior art and the predictability or lack thereof in the art:

Although the prior art of record shows the effectiveness of silver and tetrasilver tetroxide as an antimicrobial agent, the prior art of record does not appear to show that the silver or tetrasilver tetroxide is capable of treating,managing or preventing the enumerable possible dermatological skin diseases which would fall within the scope of claims

The amount of direction or guidance present and the presence or absence of working examples:

The Specification provides methods of administration and amounts but relatively few examples of effective treatment of a few dermatological conditions with tetrasilver tetroxide and does not appear to show prevention of any dermatological disease or condition.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim any dermatological skin disease. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine what other disease conditions would be effectively treated or managed and to determine that the dermatological skin diseases could be prevented.

Examiner has duly considered Applicant's arguments but deems them unpersuasive. Applicant argues that that it has shown twelve working examples illustrating the treatment, prevention or management of a variety of dermatological skin diseases or disorders. However, none of the examples show prevention only treatment or management of the identified skin diseases or disorders. Further, only two examples of non-pathogenic, dermatological skin conditions are shown, atopic dermatitis and diabetes induced foot ulcers (the other examples indicate infection or do not rule out infection as a cause of the condition). Applicant has not

shown how prevention of a dermatological condition can be visually observed if prevention is intended to prevent the dermatological condition from occurring. The mere absence of a dermatological condition does not prove that the same was prevented. Arguments of counsel do not constitute evidence. For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See In re Knowlton, 183 USPQ 33, 37 (CCPA 1974); In re Wiseman, 201 USPQ 658 (CCPA 1979).

Claim Rejections - 35 USC § 102/103

Examiner notes that the rejections under this section herein are not applicable to subject matter which was allowed in U.S. 6,258,385.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-9, 12-15, 22, 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Antelman (U.S. Pat, 5,571,520).

Antelman expressly discloses a dermatological cream containing 100 ppm sodium persulfate and 10 ppm of tetrasilver tetroxide crystals which is applied to the skin to treat a

"staph" infection falling within the scope of applicant's claims (Column 2, lines 65-68, Column 3, lines 1,2).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant does not provide evidence which shows that the claim limitation "adheres to skin" or "semi-solid" excludes a dermatological cream or that "substantially free of added persulfate" excludes the amount of persulfate in the prior art dermatological cream. The cream is applied to the skin, as such, the cream will adhere to the skin. Further, Applicant's Specification indicates that the "substantially free" means that the claimed invention can include up to about 10% of added persulfate which clearly does not exclude 100 ppm of persulfate.

Claims 1-3,5-22, 26 are rejected under 35 U.S.C. 103(a) as obvious over Antelman (U.S. Pat. No. 5,571,520) in view of the acknowledge prior art, De Cuellar et al. (US Pat. 4,828,832), Fox, Jr., et al. (US Pat. 5,334,588), Dorland's (28th Ed. 1994), The Merck Manual (16th Ed. 1992), and Remington's (17th Ed. 1985).

Antelman teaches methods of treating dermatological conditions or diseases containing a molecular crystal device which is effective against bacteria, fungi, viruses and algae (Column 1, lines 44-47, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36). It is taught that said device consists of a single crystal of tetrasilver tetroxide and that several hundred

thousand trillion of these devices may be employed in concert for their bactericidal, fungicidal and algicidal properties and in various pharmaceutical formulations and therapies (Column 1, lines 44-52). A dermatological cream and douche containing 10 PPM, a solution containing 100 PPM, and a suspension of 25%, of said devices are taught (Column 2, lines 64-68, Column 3, lines 12-14, Column 4, lines 28, 29, 34). It is taught that amount of said devices contained in the formulations was determined by the minimal concentration of tetrasilver tetroxide required to inhibit the microorganism in nutrient broth (Column 2, lines 39-44).

Applicant acknowledges that it is known that tetrasilver tetroxide is effective against a wide spectrum of pathogens, including bacteria, algae, mold and the AIDS virus (Pg. 3, lines 22-36, Pg. 4).

De Cuellar et al. teach that silver oxide is effective against, pressure ulcers, chafing, impetigo, furunculosis sycosis of the beard, infected eczematous dermatitis, purulent acne, and postulous psoriasis, and that silver oxide compound avoids the side effects of silver sulfadizine therapy (Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, lines 15-47).

Fox, Jr., et al. teach that silver compounds are effective against herpes simplex and herpes zoster and that silver oxide may be used in place of silver sulfadiazine (Column 2, lines 33-44, Column 3, lines 26-28, 31, 32).

Dorland's teaches that cold sores are caused by herpes simplex virus type1 and that shingles is caused by herpes zoster (Pgs. 351, 759-60).

The Merck Manual teaches that warts are caused by viruses (Pgs. 2426-27).

Remington's teaches that water-washable bases or emulsion bases, commonly referred to as creams, represent the most commonly used type of ointment bases and that emulsions bases

are washable and easily removed from skin or clothing (Pg. 1574). It is taught that the oil phase of the emulsion base is typically contains petrolatum (Pg. 1574). It is taught that powders are encountered in almost every aspect of pharmacy, both in industry and in practice (Pg. 1585) Various methods of producing powders are taught, including bulk powders, such as douche powders and dusting powders (Pgs. 1585-1594, 1601). A method is taught of preparing dilutions of potent powdered drugs wherein the drug is intimately mixed with a suitable diluent (Pgs 1601, 1602).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the formulation of tetrasilver tetroxide dispersed in a petroleum jelly base or as a powder, and methods of treating eczema, psorisasis,dermatitis,ulcers, shingles, rashes, bedsores, cold sores, blisters, boils, herpes, acne, pimples and warts with tetrasilver tetroxide. However, the prior art amply suggests the same as methods of preparing formulations, such as powders and creams, containing drugs, are well known in the art, and methods of treating dermatological conditions or diseases containing tetrasilver tetroxide are known in the art (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; Remington's, Pgs. 1574, 1585-94, 1601, 1602). Furthermore, the prior art teaches equivalents, active ingredients, amounts and/or method steps which are close enough, overlap or are within the range and specific limitations of the claimed invention such that one of ordinary skill in the art would expect them to have the same properties (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60, Remington's, Pgs. 1574, 1585-94,

1601, 1602). As such, it would have been well within the skill of one of ordinary skill in the art to employ various amounts of the active ingredients and method steps depending on end utility including amounts and method steps that fall within the scope of the claimed invention, because the same found in the prior art are fairly encompassed by or are close to the range and specific limitations of the claimed invention. Also, it would have been well within the skill of one of ordinary skill in the art arrive at the various amounts and/or ranges of tetrasilver tetroxide by optimization of the prior art conditions (Antelman, Column 2, lines 39-44). It would have been well within the skill of and one of ordinary skill in the art would have been motivated to treat cold sores, herpes, shingles and acne by applying tetrasilver tetroxide with the expectation that tetrasilver tetroxide would be effective as silver compounds, including silver oxide, are known to be effective in treating acne, herpes zoster and herpes simplex, and that warts are caused by viruses, therefore, it would have been expected that tetrasilver tetroxide, which is known to be a broad spectrum biocide, would also be effective (De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60; The Merck Index, pg. 2426-27). Also, one of ordinary skill in the art would have been motivated to employ a silver oxide compound, i.e. tetrasilver tetroxide, instead of silver sulfadiazine as tetrasilver tetroxide would be expected to have less side effects (De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2). Further, one of ordinary skill in the art would have been motivated to modify the prior art as above so as to employ a pharmaceutical formulation which is effective against a wide variety of dermatological pathogens and utilizes common industrial/pharmaceutical methods of preparing powders and creams (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3,

lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60; The Merck Index, pgs. 2426-37; Remington's, Pgs. 1574, 1585-94, 1601, 1602).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In the first instance, Applicant's Specification discloses that "substantially free" means that the claimed invention can include up to about 10% of added persulfate. Applicant argues that the examples in Antelman include high concentrations of sodium persulfate, however, none of the examples disclose use of sodium persulfate which is greater than about 10%. It is immaterial that the ratio of persulfate to tetrasilver tetroxide is high since the limitation relative to persulfate has nothing to do with said ratio. The limitation only requires that the total amount persulfate in the composition be less than 10%. Further, Antleman clearly discloses embodiments in which no oxidizing agent or persulfate is added (Examples 3-7). As such, it would be well within the skill of and one of ordinary skill in the art would have been motivated

to prepare other formulations, including creams, without adding an oxidizing agent, such as persulfate, with the expection that formulation without the presence of persulfate would be effective in treating the skin conditions, such as athlete's foot or toenail fungus.

Contrary to Applicant's arguments, De Cuellar et al. does not require the presence of an oxidizing agent (Column 2, lines 33-40). It is only if the oxidizing agent is present that the concentration should be at least 1%. Notwithstanding the same, a concentration of 1% is clearly less than about 10%, as such, the amount of oxidizing agent is clearly within the claim limitation relative to persulfate. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 191 USPQ 90 (CCPA 1976); In re Woodruff, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); In re Geisler, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that suitable protection' is provided if the protective layer is about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range."). Finally, De Cuellar et al. clearly indicates that the addition of the oxidizing agent is optional (Column 2, lines 33-40).

The fact that DeCuellar et al., Fox , Jr. et al., Dorland's, Merck Manual or Remington's does not disclose tetrasilver tetroxide substantially free of persulfate does not overcome the

rejection. As indicated above, the rejection is based on a combination of references, as such, each individual reference is not required by itself to disclosed the claimed invention so long as the combined teachings suggest or disclose and motivate one of ordinary skill in the art to arrive at the claimed invention. The prior art rejection as a whole as indicated above discloses the use of tetrasilver tetroxide without the use of added persulfate. , as such, the rejection herein is maintained.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

June 19, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600